REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 28-51 are pending after entry of the amendments set forth herein.

Claims 1-27 are canceled without prejudice to renewal.

New claims 28-51 are added. Exemplary support for these new claims is found in the specification at, for example, paragraphs [0041] (last sentence); [00146] (bi- ("di-") and tri-allelic markers); [0065] (last sentence); and in the original claims as set out in the table below:

Claim No.	Exemplary Support
28	Original claims 1-4
29	Original claim 5
30-31	Table 1; Table 2
32-33	Table 1; Table 4
34-35	Table 1; Table 2; Table 4
36-37	Table 1; Table 4
38-39	Table 1; Table 4
40-41	Table 1; Table 4
42-43	Table 1; Table 4
44-45	Table 1; Table 2
46-47	Table 1; Table 4
48-49	Table 1; Table 4
50	Original claim 27
51	Specification paragraphs [0082] – [0084]

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

Response to Restriction Requirement

The Office Action restricted the claims into two different Groups, and further set out an additional restriction requirement based on a combination of polymorphic markers. The requirement as it relates to the restriction based on a combination of polymorphic markers is respectfully traversed.

As to the first aspect of the restriction requirement, applicants elect Group I, claims 1-9, 12-17, and 27, drawn to method for determining the ethnic origin of a male and for determining the paternity of a human male through the detection of nucleic acids. The remaining claims – claims 10-11 and 18-26 are canceled.

Claims 1-9, 12-17 and 27 are canceled without prejudice, and new claims 28-51 corresponding to the subject matter of elected Group I are presented.

Applicants traverse the restriction requirement as to the second aspect – the requirement that the claims be limited to a particular combination of polymorphic markers. Withdrawal of this aspect of the restriction requirement is respectfully requested.

The Office Action at page 3 states:

> In accordance with MPEP 803.04, applicant is required to select one combination of polymorphic markers for examination with the elected group from those markers set forth in Table 1. Upon election of the single combination of polymorphic markers, applicant should identify where in the appropriate table each sequence is recited and applicant should further identify the single haplotype to which the group of polymorphic markers belong and further to the single primer pair used to amplify each of the polymorphic markers in the elected group. If the single combination selected by applicant contains more or less than the number of markers recited in a particular claim, the relevant claims will be treated as non-elected claims, as appropriate. For example, if the combination of claim 13 is elected, claims 14, 15, and 16, will be considered as non-elected claims. Additionally, if the combination in claim 13 of only M91, M60, and M96 were elected, then claim 13 would be non-elected because it requires a different combination. Applicant must clearly define their election with respect to the corresponding SEQ ID NOS that they are electing and the positions of each of the polymorphic markers in the SEQ ID NOS.

(emphasis added)

As noted in the Office Action, restriction of claims that recite nucleotide sequences is discussed in MPEP §803.04. MPEP §803.04 sets out guidelines for the restriction of claims directed to nucleotide sequences. Three examples of "typical nucleotide sequence claims" impacted by the Commissioner's partial waiver of 37 CFR §1.131 *et seq.* are provided as follows:

> (A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;
>
> (B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and
>
> (C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

The claims of the instant case, if analogous at all (see below), are analogous to claims of (C).

The MPEP §803.04 goes on to state:

> Applications containing only **composition claims** reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.
>
> In applications containing all three claims set forth in examples (A)-(C), the Office will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example (A), all combinations, such as in examples (B) and (C), containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.
>
> Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and nonselected and which are limited to the allowable sequence(s) will be rejoined and examined.

First, applicants note that the claims at issue are not composition claims—they are method claims. MPEP §803.04 discusses compositions claims directed to polynucleotides.

Second, applicants respectfully submit it is well-settled that patentability of a method of using a composition does not depend upon the patentability of the composition used in the method. Indeed, where a composition is patentable, then methods of use of the patentable composition are also patentable. However, methods of using a composition can be found patentable even where the composition is old. Patentability of the method claim is not dependent upon the patentability of the composition used in the method.

Given this, applicants submit that patentability of the claimed method need not depend upon the patentability of the markers recited, or of any particular combination of markers. Thus, the search required to determine the patentability of the method claims need not involve a search to identify prior art for each and every marker recited in the claim. If the method per se is free of the art, then any art that may be relevant to the patentability of the composition claims is not relevant to the patentability of the method. Again – the patentability of the method claim is not dependent upon the patentability of the composition used in the method.

Applicants also take exception to the implication that claims that recites use of one combination of markers is a separate invention from another claim that recites a different combination of markers – even where there is overlap in the markers used in the combinations. In applicants' view, the claimed method depends upon to what end the markers are being used, not the identity of the markers *per se*. Here the markers are being used to, for example, determine whether the male belongs to one of ten different haplogroups, each haplogroup being associated with a different geographic or ethnic origin (or set of such). Applicants submit that because the claims recite "comprising", practice of the invention using markers recited in a claim falls within the scope of the claims – even if additional markers *not* recited in the claim are used.

In order to be responsive to the restriction requirement, applicants elect the following markers for prosecution in the present application. The table below identifies the marker, its SEQ

ID NO., the haplogroup with which the marker is associated, and the exemplary primer pair noted in the specification useful in detecting the marker.

Marker	SEQ ID NO	Haplogroup	Primer Pair (SEQ ID NOS)
M91	272	I	273, 274
M249	735	II	736, 737
M96	287	III	288, 289
M174	519	IV	520, 521
M316	935	V	936, 937
M235	696	VI	697, 698
M214	636	VII	637, 638
M9	25	VIII	26, 27
M207	615	IX	616, 617
M242	714	X	714, 716

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-212.

Respectfully submitted,
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